

## **AT LAST!**

### **A doctorate designed specifically for Regulatory Professionals!**

The University of Southern California is pleased to announce the launch of its new professional doctorate program in Regulatory Science (DRS). Regulatory Science addresses the art and science of developing medical products and foods through the complex regulatory and reimbursement paths required to market such product internationally. The proposed 64-unit professional doctorate is a novel, specialized program of study that cultivates research, leadership and inquiry skills for advanced students in the emerging profession of global regulatory science. It is designed to produce graduates who have a particular expertise in strategic management, policy development and research assessment and who will work in senior positions in the public sector, academia and the medical products industry. Participants in this program will take a set of interdependent courses that extend from a strong core of basic regulatory science coursework and additionally focus on three main areas—global product strategy, product lifecycle strategy, and project and personnel management. Students admitted with advanced standing after foundational coursework at the MS level will participate as a cohort that typically has a two-year cycle of classes and an additional year of dissertation development. The program has been designed to meet the needs of individuals who are already working full-time outside of the university in positions in which they have substantial leadership or managerial responsibilities. The doctoral degree will be administered by the School of Pharmacy. For more information see our website, [regulatory.usc.edu](http://regulatory.usc.edu), or discuss the program with our program manager, at 323-442-3102, [regsci@usc.edu](mailto:regsci@usc.edu).



## Why a Doctorate in Regulatory Science?

Foods, drugs and medical devices have been regulated for more than a century. In the last decade, however, we have seen dramatic change in the level of preparation needed for effective management in this sector. Societal concerns over safety, globalization and technological innovation have increased the amount and detail of administrative law in the US and other areas of the world. At the same time, the increased sophistication of medical products has driven out the generalist; now regulatory leadership depends on a constellation of skill sets in science, law and management. Individuals who will lead the regulatory teams of the future must possess critical thinking skills and research acumen to be able to evaluate their own product and position it in a crowded marketplace. At the same time, they must possess a strong knowledge of policy and law, and must be able to work with large and diverse teams of individuals with different specializations and work cultures. In a recent market survey in which industries were asked what were the skill sets that need to be developed in regulatory leaders, attention was drawn to three types of capabilities: outstanding people and project management skills, a good capability to understand and work within transnational organizations to make globally relevant decisions, and a broader knowledge of policy and business than is typically acquired at junior and midlevels of the regulatory career structure. A further pressing problem is the graying of the current high-level regulatory professional. Most of the current leadership in Regulatory Science comes from individuals on the verge of retirement. These individuals learned on-the-job slowly as the regulations developed and now are leaving the field; the next generation of leaders will not have the same luxury.

Up to the present, a number of MS programs in Regulatory Science have been developed, but these are designed to educate practitioners in early career stages. What is needed now is a more advanced program that generates leaders equipped with tools and knowledge appropriate to individuals in the upper echelons of the profession where they command many subordinates and take responsibility for decisions that steer policy or company strategies. Our interest in developing the first US professional doctoral degree in Regulatory Science responds to requests made to us both from industries who are interested in recruiting and further training regulatory talent and from the professional organizations in this sector who see a strong need for strategic and research training to support policy and business decision-making. Like other professional doctorate degrees in education and policy studies, our goal is to develop individuals who can serve as leaders. However, in this case, those leaders are needed as a part of the health care system, where they will oversee the development and commercialization of medical devices, pharmaceuticals and foods, and will lead companies and government agencies concerned with regulatory planning and policy. These are the individuals who will replace the previous generation of regulatory experts, but they must be broader than most current experts. The products that they will foster, and the culturally and economically diverse countries in which they must operate, present a paradigm shift of a kind that this industry has not seen before. If we are to assure that new technologically sophisticated products make it to the marketplace, we must find new ways of benchmarking best practices and shortening the critical path that now exceeds a decade for most innovative pharmaceuticals and devices. Our vision is coherent with that of the NIH and FDA whose Roadmap Initiative and Critical Path activities stem from strong concern about the ability to sustain growth in this sector using old methods.

## **What is the admissions process?**

Students entering the DRS program must complete 64 units of specified coursework. Students will typically take a series of courses that are foundational for both the MS and DRS degree. Most students will enter after first registering in the MS Regulatory Science program. After taking a minimum of 15 units in Regulatory Science, students with good academic standing and strong leadership skills will be allowed to apply to the doctoral program. Students from the MS (Regulatory Science) program can use the credits earned in the MS program toward their subsequent requirements in the doctoral program. Also eligible for the doctoral program are students who have already taken graduate studies elsewhere either in Regulatory Science or complementary program. Students entering as advanced placement students can apply relevant units from their previous MS studies toward the doctoral program according to the transfer of credits rules of USC. Students who do not come from an MS program in Regulatory Science must be prepared to take supplementary courses in order to ensure that their foundational regulatory background is adequate. This will be ascertained on an individual basis according to evaluations by the selection committee and recommendations of the advisory committee for that student. Most students will take the courses that are listed in the sample student program below, but if students have strong previous experience in some area of study, other appropriate graduate courses may be substituted with the permission of the program director.

## **What must I do to graduate?**

Students will take a written examination after they complete the foundational courses.. The doctoral degree will typically be completed within 5 years of entry from the beginning of the program. Students will be monitored throughout the program on a term by term basis to ensure that they maintain an appropriately high GPA of 3.0 or above; failure to maintain this GPA for two consecutive terms will normally result in dismissal from the program. By the end of the program, we anticipate that the students will not only have a mature and detailed understanding of the regulations underlying global regulatory affairs, but a strong understanding of managerial tools, policy setting mechanisms and strategic decisionmaking in the medical products and foods sectors. In addition, they should understand the basic tenets of research and analysis as evidenced by their thesis submission, which will be typically focused on policy, best-practices or organizational management. Graduation depends upon the successful completion of coursework with a minimum GPA of 3.0, and the successful defense of a dissertation.

## How will the program be structured?

The program is organized as a series of modules with different foci. Students must take a minimum number of credits in each focus, and then can add additional elective courses from a broader portfolio of appropriate offerings taught in the School of Pharmacy and other Schools in the University. We encourage students to take at least a few courses in other Schools so that they develop a broader perspective and interdisciplinary appreciation, but aim to offer a sufficient richness of courses to meet the needs of our doctoral students within our School, should timetabling issues preclude the option of courses outside of the School of Pharmacy that might be given only during the normal working week.

- **Foundational courses in Regulatory Science** (minimum 15 units): These form the base and would typically be composed of core courses to the MS program or equivalent courses from graduate programs elsewhere.
- **Product Lifecycle Strategy** (minimum 8 units): A number of courses in this grouping are offered by the School of Pharmacy, either through Regulatory Science or through the Titus Family Department of Clinical Pharmacy and Pharmaceutical Economics and Policy. Students are also encouraged to take courses outside of the Pharmacy School when more specialized courses fit their personal research or professional plans.
- **Project and Personnel Management** (minimum 8 units): Three courses in this area are currently offered by the Regulatory Science program and two additional courses are proposed as part of this submission. The Marshal School of Business and School and School of Policy, Planning and Development offers additional opportunities for coursework in this area.
- **Global Regulatory Strategy and Policy** (minimum 8 units): The School of Pharmacy, including the Regulatory Science program, has designed an exciting set of globally oriented courses. The School of Policy, Planning and Development has additional courses that might also be useful for selected students according to their particular research and professional interests.
- **Research and dissertation preparation and completion** (10+ units): All students will complete a professional dissertation that starts with at least one course in research design. We currently offer two such courses, one in basic/social sciences methodology and the other in clinical study methodology. Students must take at least one of these courses in preparation for their dissertation research. Research will be concerned with specific aspects of regulatory science, such as policy, administration, best practices or ethics. The students will work in subgroups of 3-4 as they develop their research projects, and will meet regularly in this group with their advisory team to discuss progress and challenges. Each student will be mentored by two identified advisors, one from university graduate faculty and the other an industry or government supervisor/mentor who normally is appointed as an adjunct in the School. Each student must produce and defend an independent dissertation as a requirement of graduation.